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ARMY ENVIRONMENTAL HYGIENE AGENCY ABERDEEN PROVING GR--ETC F/G 6/20
TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT REPELLENT--ETC(U)
SEP 79 A W SINGER
UNCLASSIFIED USAEHA-75-51-0880-79

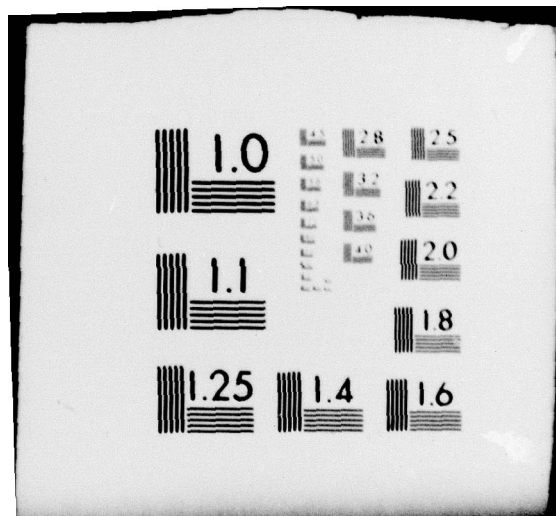
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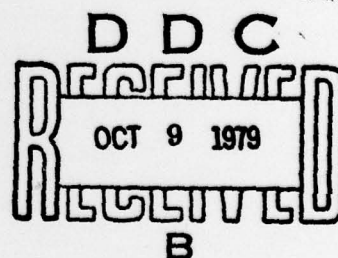
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**UNITED STATES ARMY
ENVIRONMENTAL HYGIENE
AGENCY**

ABERDEEN PROVING GROUND, MD 21010

TOPICAL HAZARD EVALUATION PROGRAM
OF CANDIDATE INSECT REPELLENT AI3-36383
US DEPARTMENT OF AGRICULTURE PROPRIETARY COMPOUND
STUDY NUMBER 75-51-0880-79
MAY 1976 - JUNE 1979



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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) A hazard evaluation of candidate insect repellent AI3-36383 was performed by means of laboratory studies using rabbits and guinea pigs. The technical grade compound caused mild skin irritation, but no eye irritation. It also produced a mild sensitization reaction in two of ten test guinea pigs.		



DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

CPT Singer/cw/AUTOVON
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HSE-LT-T/WP

12 SEP 1979

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellent
AI3-36383, US Department of Agriculture Proprietary Compound, Study
No. 75-51-0880-79, May 1976 - June 1979

Executive Secretary
Armed Forces Pest Control Board
Forest Glen Section, WRAMC
Washington, DC 20012

A summary of the pertinent findings and recommendations of the inclosed report follows:

A hazard evaluation of candidate insect repellent AI3-36383 was performed by means of laboratory studies using rabbits and guinea pigs. The technical grade compound caused mild skin irritation, but no eye irritation. It also produced a mild sensitization reaction in two of ten test guinea pigs. It was recommended that AI3-36383 not be approved for further testing as a candidate insect repellent. In the event that this compound presents a significant improvement in pest repellent properties over existing compounds, it is suggested that AI3-36383, US Department of Agriculture Proprietary Compound, be either purified or reformulated at its proposed use concentration and resubmitted for further testing.

FOR THE COMMANDER:

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TOPICAL HAZARD EVALUATION PROGRAM
OF CANDIDATE INSECT REPELLENT AI3-36383
US DEPARTMENT OF AGRICULTURE PROPRIETARY COMPOUND
STUDY NUMBER 75-51-0880-79
MAY 1976 - JUNE 1979

1. AUTHORITY.

a. Letter, US Department of Agriculture - Agricultural Research Service, Southern Region, Insects Affecting Man Research Laboratory, Gainesville, Florida, 5 May 1976.

b. Memorandum of Understanding between the Department of the Army; Office of The Surgeon General; the US Army Health Services Command; the US Army Environmental Hygiene Agency; the Armed Forces Pest Control Board; and the US Department of Agriculture, effective 1970 with Amendment No. 1, effective August 1974.

2. REFERENCE. Toxicology Division Procedural Guide, USAEHA, 1972, revised 1976.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-36383.

4. SUMMARY OF FINDINGS. A hazard evaluation of the candidate insect repellent AI3-36383, US Department of Agriculture (USDA) Proprietary Compound, was conducted by this Agency using New Zealand White rabbits for skin and eye studies and Hartley guinea pigs for a skin sensitization study. A tabular presentation of animal toxicity data developed in this Agency follows.*†

* In conducting the studies described in this report, the investigators adhered to the "Guide for the Care and Use of Laboratory Animals," US Department of Health, Education, and Welfare Publication No. (NIH) 74-23, revised 1972.

† The experiments reported herein were performed in animal facilities fully accredited by the American Association for Accreditation of Laboratory Animal Care.

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Test	Results	Interpretation
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SKIN IRRITATION STUDIES

Rabbits

Single 24-hour application to intact and abraded skin of New Zealand White rabbits.

Compound A13-36383 produced mild primary irritation of the intact skin and the skin surrounding an abrasion.

USAEHA Category II (ref Appendix).

0.5 ml technical grade compound applied to each of six rabbits.

EYE IRRITATION STUDIES

Rabbits

Single 24-hour application of 0.1 ml technical grade compound to one eye of each of six New Zealand White rabbits.

Compound A13-36383 did not produce any injury to the cornea and no injury to the conjunctiva in six out of six rabbits.

USAEHA Category A (ref Appendix).

Two of six rabbits did, however, vocalize upon administration of the compound.

Vocalization may indicate pain or distress to the animal.

SENSITIZATION STUDIES

Guinea Pigs (Male)

Intradermal injections of 0.1 ml of a 0.1 percent suspension (w/v) of A13-36383 or of dinitrochlorobenzene (DNCB)* in a mixture containing one volume of propylene glycol and 29 volumes of saline.

Ten test guinea pigs were given ten sensitizing doses, followed by a challenge with a 0.1 percent solution of A13-36383.

Challenge dose of test compound (last intradermal injection) produced mild sensitization reaction in two of ten test guinea pigs.

Compound A13-36383 can sensitize guinea pigs and may cause a similar reaction in man.

Ten positive control guinea pigs were sensitized and challenged with 0.1 percent suspension of DNCB.

Positive control (DNCB) produced a marked sensitization reaction in 9 out of 10 guinea pigs.

* A known skin sensitizer.

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5. CONCLUSION. Technical grade compound AI3-36383 causes mild primary skin irritation and may cause skin sensitization reactions in certain individuals. As such, it does not qualify as a nonhazardous insect repellent.

6. RECOMMENDATION. Under the provisions of the Memorandum of Understanding (paragraph 1b) it is recommended that AI3-36383, USDA Proprietary Compound, not be approved for further testing as a candidate insect repellent. Only if this compound shows significant improvement in pest repellent properties over existing compounds should further action be taken, such as activated charcoal treatment, and resubmission in its proposed use formulation and concentration.



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APPROVED:



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APPENDIX

TOPICAL HAZARD EVALUATION PROGRAM
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING
CONSIDERED FOR ACUTE SKIN APPLICATION

CATEGORY I - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin.)

CATEGORY II - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.)

CATEGORY III - Compounds producing moderate primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin. May be used without patch testing, with extreme caution, as clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration so that its irritation potential can be reexamined using other test techniques on animals.)

CATEGORY IV - Compounds producing moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation, and/or eschars. (INTERPRETATION: Should be resubmitted for testing in the form and at the intended use concentration. Upon resubmission, its irritation potential will be reexamined using other test techniques on animals, prior to possible prophetic patch testing in humans, at concentrations which have been shown not to produce primary irritation in animals.)

CATEGORY V - Compounds impossible to classify because of staining of the skin or other masking effects owing to physical properties of the compound. (INTERPRETATION: Not suitable for use on humans.)

EYE CATEGORIES:

A. Compounds noninjurious to the eye. INTERPRETATION: Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.

B. Compounds producing mild injury to the cornea. INTERPRETATION: Should be used with caution around the eyes.

C. Compounds producing mild injury to the cornea, and in addition some injury to the conjunctiva. INTERPRETATION: Should be used with caution around the eyes and mucosa.

D. Compounds producing moderate injury to the cornea. INTERPRETATION: Should be used with extreme caution around the eyes.

E. Compounds producing moderate injury to the cornea, and in addition producing some injury to the conjunctiva. INTERPRETATION: Should be used with extreme caution around the eyes and mucosa.

F. Compounds producing severe injury to the cornea and to the conjunctiva. INTERPRETATION: Should be used with extreme caution. It is recommended that use be restricted to areas other than the face.